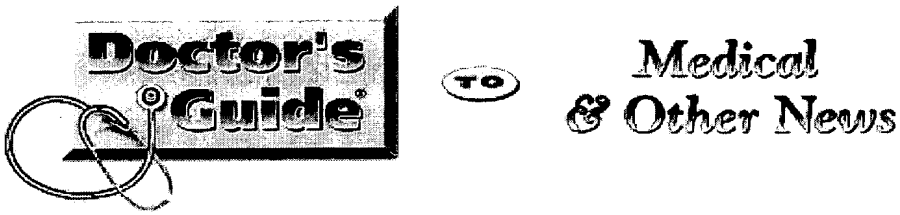

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Title: **FDA Approves Cosopt Combination Eye Drops**
URL: http://www.pslgroup.com/dg/6B946.htm
Doctor's Guide
April 8, 1998

WEST POINT, PA -- April 8, 1998 -- The United States Food and Drug Administration has granted marketing clearance to Merck & Co., Inc.'s Cosopt(TM) (dorzolamide hydrochloride-timolol maleate ophthalmic solution), the first eye drop that combines a topical carbonic anhydrase inhibitor and a topical beta-blocking agent, effective ophthalmic products with excellent safety profiles.

Cosopt is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who do not respond adequately to beta-blockers alone.

Both components of Cosopt are leading therapies in their product categories and are currently available from Merck as individual medicines under the brand names Trusopt(R), (dorzolamide hydrochloride ophthalmic solution), introduced in 1995 and Timoptic(R) (timolol maleate ophthalmic solution). Timoptic was approved in 1978. Each of the two components decreases elevated intraocular pressure in patients with open-angle glaucoma by reducing the secretion of fluids inside the eye.

Elevated intraocular pressure is a major risk factor for glaucoma and it is associated with irreversible damage to the optic nerve. The optic nerve conveys messages from the eye to the brain. High intraocular pressure predisposes susceptible individuals to permanent optic nerve damage and loss of vision. The higher the intraocular pressure, the greater the likelihood of loss of vision from glaucoma.

In clinical studies, Cosopt administered twice a day produced reduction in intraocular pressure greater than that seen when either Trusopt or Timoptic was used as sole therapy. The reduction was slightly less than that seen when both were used individually in a concomitant daily treatment regimen of Trusopt three times daily and Timoptic twice daily.

Merck estimates that more than half of all patients being treated for glaucoma are currently taking more than one topical medication to control their eye pressure. Simplifying multiple drug regimens is particularly important since these patients may remain on therapy for many years.

"We see this combination as a welcome addition to the treatment options for glaucoma," said Robert Allen, M.D., professor and chairman of the department of ophthalmology at the Medical College of Virginia Campus of Virginia Commonwealth University and a principal investigator on the clinical trials for this product.

"This new combination offers appropriate, effective treatment and the convenience of two daily doses

with just one drug regimen. This is a real advantage."

Glaucoma is a leading cause of preventable blindness and is often called the sneak thief of sight. Between two and three million people over the age of 40 have some form of glaucoma and at least half of them aren't even aware that they have it. Those with glaucoma usually do not notice any signs or symptoms of the disease until their vision has already been affected.

Patients at risk for glaucoma include those with increased intraocular pressure and those who are African Americans. The risk for glaucoma also increases with age. African Americans over the age of 40 and Caucasians over the age of 60 are at an increased risk for developing glaucoma. Others include those with blood relatives who have glaucoma, those who have had eye injuries, and anyone who has used steroid medications for extended periods of time.

Cosopt is contraindicated in patients with bronchial asthma and in those with a history of bronchial asthma, as well as in those with severe chronic obstructive pulmonary disease, certain heart conditions, or hypersensitivity to any component of the product.

During clinical studies, the most frequently reported adverse events associated with the use of Cosopt were burning and/or stinging of the eyes and changes in taste in up to 30 percent of patients, however, only five percent of patients discontinued drug therapy as a result of adverse events.

Cosopt is available only as an eye drop. The dose is one drop in the affected eye(s) twice daily. Each millilitre of the product contains 20 mg dorzolamide and 5 mg timolol.

More information on: Merck & Co., Inc..

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